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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,594	10/31/2006	Chikako Takatoh	TAKATOH1	2977

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EXAMINER	
PANDE, SUCHIRA	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,594	TAKATOH ET AL.	
	Examiner	Art Unit	
	SUCHIRA PANDE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Amendment filed on March 11, 2009 is acknowledged. Applicant has cancelled claims 1-3, 5 and 8; claims 4 and 7 are amended. Currently claims 4, 6 and 7 are pending and will be examined in this action.

Response to Arguments

Re 103 rejection of claims 4, 6 and 7 over Larsson et al. in view of Juarrenz et al.

2. Applicant's arguments with respect to claims 4, 6 and 7 have been considered but are moot in view of the new ground(s) of rejection. Applicant has amended claims 4 and 7 to add new limitations that change the scope of the claimed invention. New art is being cited that addresses this changed scope. Hence the previously cited rejections of claims 4, 6 and 7 over Larsson et al. in view of Juarrenz et al. is being withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaylord et al. (January 1, 2003) J. Am. Chem. Soc. vol. 125, pp 896-900 (newly cited) in view of Juarrenz et al. (April 1996) J. of microscopy vol. 182, Pt. 1, pp. 46-49 (previously cited and provided by Applicant in IDS) as evidenced by Seokjoo Hong and Sungho Huh (2003) Bull. Korean Chem Soc. Vol. 24: no. 1 pp 137-140 (provided by Applicant in IDS).

Regarding claim 4, Gaylord et al. teach a method for detecting the presence of a target single- stranded nucleic acid in a sample (see title) comprising:

contacting a sample suspected of containing a target single-stranded nucleic acid with a nucleic acid probe that is a DNA fragment or a chemically synthesized DNA comprising a nucleic acid sequence complementary to the target single-stranded nucleic acid, under hybridization conditions whereby a double-stranded hybrid nucleic acid composed of said nucleic acid probe and said target nucleic acid will be formed if the target nucleic acid is present in the sample, (see page 900 Experimental section where ssDNA target (complementary) is mixed with probe sequence 2-C*. Followed by annealing to hybridize the sstarget complementary DNA strand with the probe 2-C*. Hybridization of complementary target with the probe to form the hybrid (target + probe) was verified using melting curve analysis. Thus Gaylord et al. teach contacting a sample suspected of containing a target single-stranded nucleic acid with a nucleic acid probe

that is a DNA fragment or a chemically synthesized DNA comprising a nucleic acid sequence complementary to the target single-stranded nucleic acid, under hybridization conditions whereby a double-stranded hybrid nucleic acid composed of said nucleic acid probe and said target nucleic acid will be formed if the target nucleic acid is present in the sample),

binding a cationic dye compound onto any hybrid nucleic acid formed in said contacting step by adding the cationic dye compound before, during or after said contacting step, (see page 896 abstract where water soluble cationic dye represented by formula 1 cationic conjugated polymer (CP) is shown. By teaching cationic conjugated polymer Gaylord et al. teach a cationic dye compound. See page 900 last par. where CP is added to samples (ssDNA complementary DNA + probe 2-C* hybrid) formed above. Thus teaching binding a cationic dye compound onto any hybrid nucleic acid formed in said contacting step by adding the cationic dye compound after said contacting step),

measuring circular dichroism of any cationic dye compound bound onto a hybrid nucleic acid, (see Gaylord et al. page 899 foot note 34 where CD experiments are described. The compound taught by Gaylord et al. when bound to DNA is subjected to Circular Dichroism (CD) measurement. The CD experiments were performed which indicated that DNA conformation does not change upon addition of CP and that CP binds to DNA largely due to electrostatic interactions. Thus Gaylord et al. teach measuring circular dichroism of any cationic dye compound bound onto a hybrid nucleic acid)

wherein the presence of said circular dichroism indicates that the sample contained target single-stranded nucleic acid. (The results of the CD spectrum will indicate if the dye is bound to a DNA hybrid (double stranded DNA) formed above. Detection of hybrid inherently indicates the sample contained target single-stranded nucleic acid that was complementary to probe).

Regarding claim 4, Gaylord et al. do not teach

wherein said cationic dye compound has the following formula

(I): X-(Y-Z)a (I)

wherein

n denotes 1 to 12,

X represents a chromophore having at least four pyrrole rings,

Y represents a connecting group or a direct bond between X and Z, and

Z represents a cationic functional group, or a functional group whose property is convertible to a cationic property; and

Regarding claims 4 and 6 Juarrenz et al. teach meso-tetra (4-N-methylpyridyl)porphine (T4MpyP) and meso-tetra (p-N-trimethylanilinium) porphine (TMAP) (see abstract) as a cationic dye compound is represented by the following general formula (I): X-(Y-Z)n. A search done in STN for these chemicals provides following structure.

```
L14   3 ANSWERS   REGISTRY  COPYRIGHT 2007 ACS on STN
IN    Pyridinium, 4,4',4'',4'''-(21H,23H-porphine-5,10,15,20-
tetrayl)tetrakis[1-
      methyl-, bis(inner salt)  (9CI)
MF    C44 H36 N8
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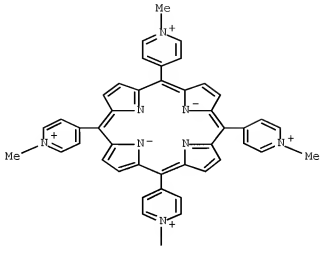
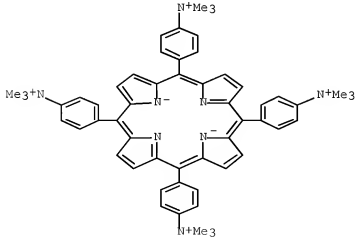
PAGE 1-A



PAGE 2-A

Me

L14 3 ANSWERS REGISTRY COPYRIGHT 2007 ACS on STN
IN Benzenaminium, 4,4',4'',4'''-(21H,23H-porphine-5,10,15,20-tetrayl)tetrakis[N,N,N-trimethyl-, bis(inner salt) (9CI)
MF C56 H60 N8



Thus regarding claim 4, Juarrenz et al. teach wherein said cationic dye compound is represented by the following general formula (I): X-(Y-Z) n

Thus regarding claim 6, Juarrenz et al. teach wherein said choromophore is selected from the group consisting of porphyrin, porphyrin derivatives.

Thus art teaches two cationic compounds that bind to DNA.

It would have been prima facie obvious to one of ordinary skill in the art to practice the method of Juarrenz et al. in the method of Gaylord et al. at the time the invention was made. The motivation to do so is provided to one of ordinary skill in the art by teachings of both Gaylord et al. and Juarrenz et al.

Both cationic dyes namely CP taught by Gaylord et al. and porphyrin derivatives taught by Juarrenz et al. are dyes that bind to DNA. TMAP is a porphyrin derivative compound of formula I recited in instant claims. This compound has an inherent property of exhibiting CD spectra when bound to DNA. In addition Juarrenz et al. teaches that this compound does not intercalate in DNA rather it's an outside binder. Thus art teaches two cationic compounds that bind to DNA without intercalating and exhibit CD spectra associated with them.

Porphyrin derivatives (TMAP) taught by Juarrenz et al. has an inherent property that it exhibits a CD spectra when bound to DNA. This is evidenced by Seokjoo Hong and Sungho Huh (2003) Bull. Korean Chem Soc. Vol. 24: no. 1 Fig. 3 on page 139 where CD spectra of TMAP is shown at various molar ratios (r) of [porphyrin]/[DNA].

Thus based on teaching of Juarrenz et al. and Seokjoo Hong & Sungho Huh one of ordinary skill in the art knows that one can measure circular dichroism of TMAP a cationic dye compound bound onto a hybrid nucleic acid. Therefore one of ordinary skill can readily use one or the other dye for binding DNA and measuring CD depending on

the experimental design and the parameter they are interested in monitoring. See MPEP 2144.06 Art Recognized Equivalence for the Same Purpose

SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaylord et al. in view of Juarrenz et al. as evidenced by Seokjoo Hong & Sungho Huh as applied to claim 4 above further in view of Minunni et al. (2001) Fresenius J. Anal Chem vol. 369: pp 589-593 (newly cited).

Regarding claim 7, Gaylord et al. in view of Juarrenz et al. as evidenced by Seokjoo Hong & Sungho Huh teach method of claim 4 above, but they do not teach a method further including, prior to said contacting step, the step of immobilizing said target single-stranded nucleic acid or said nucleic acid probe onto a solid phase carrier.

Regarding claim 7, Minunni et al. teach method including, prior to said contacting step, the step of immobilizing said target single-stranded nucleic acid or said nucleic acid probe onto a solid phase carrier. (see page 589 section introduction par. 3 where probe is taught to be immobilized on sensor surface. Thus teaching prior to said

contacting step, the step of immobilizing said nucleic acid probe onto a solid phase carrier).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to practice the method of immobilizing the probes as taught by Minunni et al. in the method of Gaylord et al. in view of Juarrenz et al. as evidenced by Seokjoo Hong & Sungho Huh. The motivation to do so is provided to one of ordinary skill in the art from the teaching of Minunni et al.

Minunni et al. teaches development of biosensors for detection of genetically modified organisms (GMOs). They state "The sensing principle is based on the affinity interaction between nucleic acids: the probe is immobilized on the sensor surface and the target analyte is free in solution. The immobilized probes are specific for most inserted sequences in GMOs." (see abstract). Minunni et al. go on to state, "Biosensors for their characteristics (i.e. fast time response, low costs) are very attractive for new applications in different emerging fields like genetically modified organisms (GMOs) detection" (see page 589 par. 1). Thus one of ordinary skill in the art has a reasonable expectation of being able to immobilize probes on different sensing surfaces and know that these immobilized probes will recognize complementary target sequences. So the hybridization of the complementary target sequences in solution to immobilized probes can be used to develop biosensors based on hybridization of the complementary target sequences to immobilized probes. One of ordinary skill in the art will expect such sensors will have the advantage of being both fast (i.e. have fast response time) and cheap (low cost).

Conclusion

7. All claims under consideration 4, 6 and 7 are rejected over prior art.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

Suchira Pande
Examiner
Art Unit 1637